

BARD

Site~Rite* 5 Ultrasound System Manufactured by:

Bard Access Systems, Inc. Salt Lake City, UT 84116 U.S.A.

(801) 595-0700

Customer Service: (800) 545-0890 Technical/Clinical Support: (800) 443-3385

Fax: (801) 595-4948 www.bardaccess.com

An issued or revision date for these instructions is included for the users information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revision date: May, 2006.

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BARD



INSTRUCTIONS FOR USE





Do not operate in the presence of flammable anesthetics



Dot Markers Active



Dangerous Voltage



Warning: Refer to Manual Before Use



Power/Stand-by



BF Type Equipment



Medical Electrical Equipment Classified by ETL with respect to Electric Shock, Fire, and Mechanical Hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1



Do Not Dispose of Battery Pack In Fire



AC Adapter



Humidity Parameters



Class II Equipment

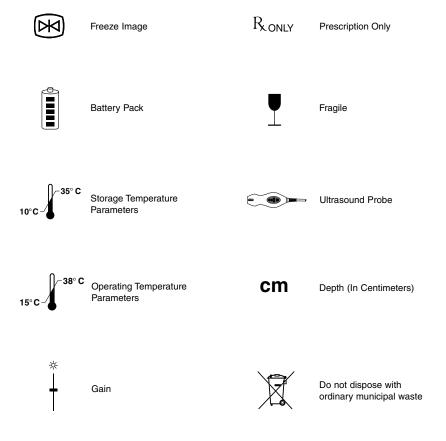


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Site~Rite* 5 System - Important Information

Warning: Do not use for ophthalmic indications. Ophthalmic use may cause patient injury.

Warning: Do not remove outer protective covers from the Site~Rite 5 scanner. Hazardous

voltages exist at several points within the system.

Warning: Only qualified personnel should attempt to service this equipment. The Site~Rite 5

contains static sensitive components and circuits. Failure to observe proper static

control procedures may result in damage to the system.

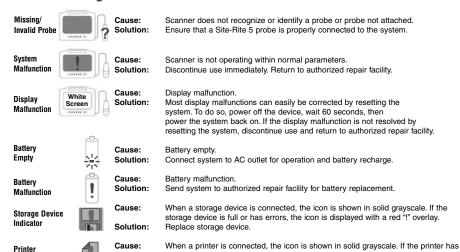
Warning: Do not allow liquid to enter the scanner, combination A/C adapter and battery

charger, probe connector or probe port. Damage to equipment may occur.

Troubleshooting & Error Screens

Solution:

Indicator



Check paper or service printer.

an error condition, the icon is displayed with a red "!" overlay.



Service and Repair

Warning: Only qualified personnel should attempt to service this equipment. The Site~Rite 5 System contains static sensitive components and circuits. Failure to observe proper static

control procedures may result in damage to the system.

Warning: The following actions void the warranty of the Site~Rite 5 Ultrasound System:

· Opening or servicing the scanner or the probe housing.

- Removal of system labels by anyone other than by Bard Access Systems authorized service personnel.
- Opening or servicing the battery pack or the combination A/C adapter and battery charger by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite 5 scanner to any power source other than the Site~Rite 5 combination A/C adapter and battery pack.
- Connecting the Site~Rite 5 scanner to any A/C adapter other than the one provided with the scanner.
- Connecting the Site~Rite 5 System to any unauthorized accessory.

For servicing information or to return your Site~Rite* 5 Ultrasound System for repair, please contact Bard Access Systems Technical / Clinical Support at (800) 443-3385.

Cleaning Procedures

To clean the scanner, probe and combination A/C adapter and battery charger:

- 1. Turn off the system.
- 2. Dampen a nonabrasive cloth with either warm water or rubbing alcohol.
- 3. Gently wipe the dampened cloth over exterior surfaces requiring cleaning.

Disinfection Procedures

The Site~Rite 5 probe may be liquid disinfected by soaking it in Cidex® plus 28 day solution.

Follow the solution manufacturer's recommendations for soak time necessary to achieve the desired germicide level of activity.

Warning: Do not allow liquid to enter the scanner, combination A/C adapter and battery charger,

probe connector or probe port. Damage to equipment may occur.

Warning: Do not attempt to sterilize the Site~Rite 5 scanner or probes with ethylene oxide or

heat sterilization methods. Damage to the equipment may occur.

Caution: When disinfecting the probe with a liquid disinfectant, do not soak

the probe cable, cable bend relief, probe connector or probe

buttons. Doing so may damage the probe.

Caution: Hot water (in excess of 113°F or 45°C) may damage the probe.

Caution: Use only Bard Access Systems cleaning and disinfection procedures. Failure to do so may

damage the device.

Note: When cleaning the system and components, it is important to remove all particles or other

matter from all surfaces and crevices.

1 Overview



The Site~Rite 5 Ultrasound System with associated probe and accessories provide ultrasound guidance for placement of needles and catheters in vascular structures. Ultrasound guidance may occur intraoperatively or percutaneously. Ultrasound imaging of vascular structures, various organs and structures of the body may also be performed.

1.2 Site~Rite* 5 Ultrasound System and Components

The Site~Rite 5 Ultrasound System is an easy to use and portable ultrasound scanner.

Site~Rite 5 Ultrasound System and Accessories include:

- Site~Rite 5 scanner
- Site~Rite vascular access probe
- Site~Rite standard roll stand
- Site~Rite collapsible roll stand
- Site~Rite VAD bedside roll stand
- Site~Rite 5 printer
- Site~Rite needle guides
- Site~Rite disposable probe covers
- Combination Site~Rite A/C adapter and battery charger
- · Roll stand mounted battery
- Ultrasound gel
- · Ultrasound vessel phantom

Contact your Bard Access Systems' Sales Representative or Customer Service at (800) 545-0890 to order.

1.3 Warnings, Precautions and Notes

Warnings

Warning: This product should only be operated by qualified medical personnel.

Warning: Do not remove outer protective covers from the Site~Rite 5 scanner. Hazardous

voltages exist at several points within the system.

Warning: Do not operate the Site~Rite 5 Ultrasound System or the Site~Rite A/C adapter and

battery charger in the presence of flammable anesthetics or gases. Explosion

may result.

Warning: Do not use for ophthalmic indications. Ophthalmic use may cause patient injury.

Warning: Misuse of the Site~Rite 5 System may result in damage to the equipment or

personal injury.

Warning: Use only the combination Site~Rite A/C adapter and battery charger to charge

Site~Rite 5. Use of any other device to charge Site~Rite 5 battery packs may damage

the battery packs and will void your warranty.

Warning: Only connect a Site~Rite 5 combination A/C adapter and battery charger to the

Site~Rite 5 System. Use of any other A/C adapter may cause intermittent or unpredictable operation, may damage the system and will void your warranty.

Warning: If a probe is damaged in any way, discontinue use immediately. Damage to the

scanner may occur.

Warning: Avoid subjecting the probe to excessive mechanical shock. Damage to the probe may

occur.

Warning: Use only Bard Access Systems probes with this system. Use of unapproved probes

may result in patient injury or equipment damage.

Warning: When using Site~Rite Needle Guides on the Site~Rite probe, use only sterile plastic

probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

Warning: Do not allow liquid to enter the scanner, combination A/C adapter and battery

charger, probe connector or probe port. Damage to equipment may occur.



Warnings (continued)

Warning: Do not attempt to sterilize the Site~Rite 5 scanner or probes with ethylene oxide or

heat sterilization methods. Damage to the equipment may occur.

Warning: Always properly dispose of dead battery packs in accordance with local regulations.

Improper disposal may present an environmental hazard.

Warning: Only qualified personnel should attempt to service this equipment. The Site~Rite 5

contains static sensitive components and circuits. Failure to observe proper static

control procedures may result in damage to the system.

Warning: The following actions void the warranty of the Site~Rite 5 System.

· Opening or servicing the scanner or the probe housing.

 Removal of system labels by anyone other than by Bard Access Systems authorized service personnel.

 Opening or servicing the battery pack or the combination A/C adapter and battery charger by anyone other than Bard Access Systems authorized service personnel.

Connecting the Site~Rite 5 scanner to any power source other than the Site~Rite 5 combination A/C adapter and battery pack.

 Connecting the Site~Rite 5 scanner to any A/C adapter other than the one provided with the scanner.

Connecting the Site~Rite 5 system to any unauthorized accessory.

Warning: Inspect A/C adapter and battery cord for damage. If any of the prongs are damaged, use battery power until replacement cord is obtained.

Warning: Verify that all accessories attached to the system comply to 60601 safety standards. Non-compliance may result in increased patient risk.

Warning: Use only IEC or ISO approved safety devices outside the patient environment. Failure to do so may damage the equipment.

Warning: Equipment that relies on basic insulation only shall not be used with this system.

Failure to comply could result in increased patient risk.

Warning: Maximum shelf load on the VAD bedside roll stand is 22 lbs. Exceeding this weight may

damage the roll stand.

Warnings (continued)

Warning: Do not overtighten screws when attaching to the VESA roll stand mount. Doing so may

damage the scanner.

Warning: Use only screws provided in packaging. Ensure the unit is secure against the VESA roll

stand mount. Failure to do so may cause the scanner to disconnect from the VESA roll

stand mount.

Warning: Do not use the probe with high frequency surgical equipment. Doing so may damage the

equipment.

Warning: Do not pull on probe cable. Doing so may cause the system to tip.

Precautions

Caution: The adverse biological effects of ultrasound on tissue appear to be threshold effects. When

tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If, however, a certain threshold has been passed biological effects may occur. While the Site~Rite 5 acoustic output parameters fall well below all FDA thresholds for adverse biological effects, any given Ultrasound Procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using

the principle of ALARA.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Caution: Do not pull the cable to disconnect the probe connector from the scanner. Pulling the

cable may damage the cable, cable connection or scanner.

Caution: Do not twist or bend the probe cable in excess of that required during normal use of the

probe. Excessive twisting or bending of the cable may cause failure, intermittent or

unpredictable operation.

Caution: When disinfecting the probe with a liquid disinfectant, do not soak the probe cable,

cable bend relief, probe connector or probe buttons. Doing so may damage the probe.

Caution: Only apply commercially available ultrasonic couplant, which has been specifically

formulated for use in medical applications, to the acoustic window (or face) of the

probe.



Precautions (continued)

Caution: Use water or rubbing alcohol and a soft cloth to remove couplant from the acoustic

window (or face) of the probe. Failure to do so may scratch the acoustic window.

Caution: Do not to allow ultrasonic couplant to dry on the acoustic window (or face) of the

probe. If the couplant should dry, use water or rubbing alcohol and a soft cloth to remove it. Never use a tool of any kind to remove dry couplant from the acoustic

window (or face) of the probe.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may

cause allergic reactions. Refer to the US FDA alert titled: "Medical Alert: Allergic

Reactions to Latex-Containing Medical Devices", issued March 29, 1991.

Bard Access Systems distributes sterile probe covers and needle guide kits that do

not contain latex.

Caution: Do not force the probe connector. Damage to the connector and system could result.

Caution: Always snap the needle guides on to the probe hook. Do not slide the needle guide

on to the needle guide hook, as the sterile sheath may tear.

Caution: Do not subject the probe to excessive vibration. Vibration may dislodge sensitive

components and cause intermittent or unpredictable operation.

Caution: Prior to each use please inspect the integrity of all power cords and connectors as

well as the integrity of the unit itself. If any problems are found please discontinue use immediately and contact an authorized service representative. Use of a damaged

power cord could damage the machine.

Caution: Unapproved extension cords should not be used with this system. Doing so may

damage the system.

Caution: During use, the AC connector needs to be easily accessible. In case of emergency

remove the power cord as soon as possible.

Caution: To avoid unnecessary strain on the user, use the device in a comfortable manner.

Precautions (continued)

Caution: Attach power source in such a way as to prevent damage. Improper installation may

damage power cords.

Caution: Inspect the probe prior to each use. If damage to the cable or transducer face is noted, do

not use the probe. Damage to the system may occur.

Caution: Hot water (in excess of 113° F or 45° C) may damage the probe.

Caution: Use only Bard Access Systems cleaning and disinfection procedures. Failure to do so

may damage the device.

Notes

Note: When cleaning the system and components, it is important to remove all particles or other

matter from all surfaces and crevices.

Note: For 240 V applications use only center tapped 240 VAC single phase power.



2 Assembling the Site~Rite* 5 Ultrasound System

Unpack the Site~Rite* 5 System and verify the contents against the packing slip. Inspect all parts for damage. If any damage is found, please contact Bard Access Systems at 800-443-3385.

2.1 Roll Stand Options



VAD Bedside Roll Stand

Warning: Maximum shelf load on the VAD bedside roll stand is 22 lbs. Exceeding this weight may damage the roll stand.



Standard Roll Stand

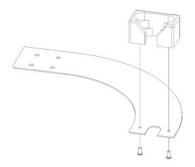


Collapsible Roll Stand

2.2 Assembling the Roll Stand

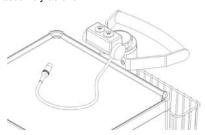
Step 1:

Attach probe holder to probe arm as shown.



Step 3:

Remove two screws from Swivel Mount assembly as shown.



Step 2:

Attach Probe Arm to monitor mounting plate using rear two holes only as shown.



Step 4:

Using two screws removed in Step 3 mount Monitor Plate and Probe Arm assembly to Swivel Mount assembly as shown.

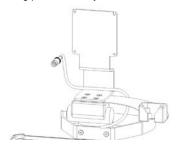




Assembling the Roll Stand (continued)

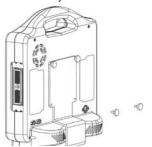
Step 5:

Route cord in the lower rear corner of monitor mounting plate assembly as shown.



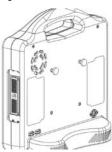
Step 7:

Slide monitor onto monitor mounting plate, insert two screws in lower mounting locations and tighten all four screws. Be sure that cable is routed below monitor and moves freely.



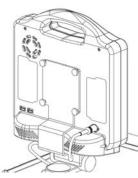
Step 6:

Start two screws in the top two monitor mounting locations as shown.

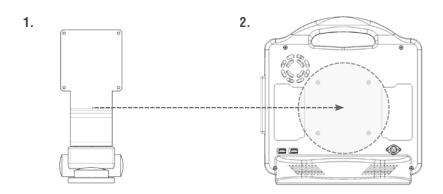


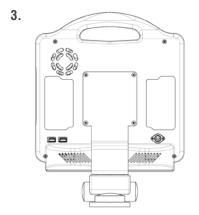
Step 8:

Plug in cord as shown.



2.3 Attaching the Site~Rite* 5 Scanner to Approved Roll Stands





Conforms to 100mm VESA Mount

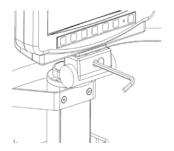
Warning: Do not overtighten screws when attaching to the VESA roll stand mount. Doing so may damage the scanner.

Warning: Use only screws provided in packaging. Ensure the unit is secure against the VESA roll stand mount. Failure to do so may cause the scanner to disconnect from the VESA roll stand mount.



2.4 Adjusting the Scanner

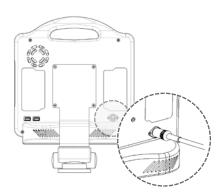
Tension Adjustment



Tilt and Swivel Adjustment



2.5 Attaching the Power Source and Charging the Battery



Warning: Use only the combination Site-Rite A/C adapter and battery charger to charge Site-Rite 5. Use of any other device to charge Site-Rite 5 battery packs may damage the battery packs and will void your warranty.

Warning: Only connect a Site-Rite 5 combination A/C adapter and battery charger to the Site-Rite 5 System. Use of any other A/C adapter may cause intermittent or unpredictable operation, may damage the system and will void your warranty.

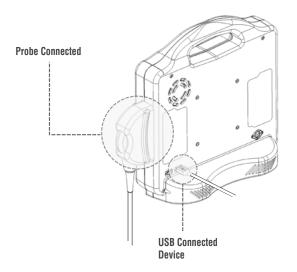
Warning: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.

Warning: Inspect A/C adapter and battery cord for damage. If any of the prongs are damaged, use battery power until replacement cord is obtained.

When the Site~Rite 5 System is attached to AC power, the battery charges automatically.

Caution: Attach power source in such a way as to prevent damage. Improper installation may damage power cords.

2.6 Connecting and Disconnecting Site~Rite* 5 Probes



Warning: Use only Bard Access Systems probes with this system. Use of unapproved probes may result in patient injury or equipment damage.

Caution: Do not pull the cable to disconnect the probe connector from the scanner. Pulling the cable may damage the cable, cable connection or scanner.

Caution: Do not twist or bend the probe cable in excess of that required during normal use of the probe. Excessive twisting or bending of the cable may cause failure, intermittent or unpredictable operation.

2.7 Powering on the Site~Rite* 5 Ultrasound System

To power on the Site~Rite* 5 Ultrasound System

- 1. Verify that the probe is connected to the Site~Rite 5 scanner.
- 2. Depress and release the power button located on the front of the Site-Rite 5 scanner.
- 3. Wait approximately 20 seconds for the display screen to illuminate.
- To power off the Site~Rite 5 System, depress and release the power button again. The system is powered off when the display screen darkens.



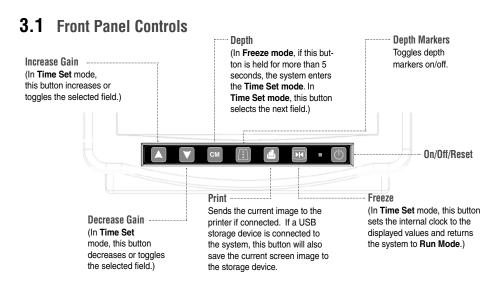
2.8 Resetting the Site~Rite* 5 Ultrasound System

Should the scanner display ever appear blank or show an exclamation mark (!), the system may need to be reset.

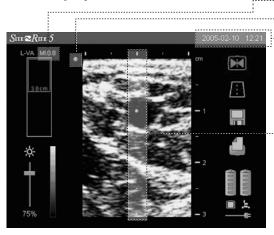
To reset the system:

- 1. Depress and release the power button located on the front of the Site~Rite 5 scanner.
- 2. Wait approximately 60 seconds for the unit to reset itself.
- 3. Power the unit back on per instructions in section 2.7.

3 Site~Rite* 5 System Information



3.2 Display Screen Information



····· Mechanical Index

The mechanical index is shown in increments of 0.1 with an accuracy of +/- 0.09.

Probe Orientation Marker

Time and Date

The time is shown in 24 hour "00:00:" format and the date may be displayed in MM/DD/YY or DD.MM.YY format.

Image Depth Markers

When enabled, the depth markers are shown as green dots superimposed on the image at 1.0 cm pitch with smaller dash marks at 0.5 cm.



Probe Depth Indicator Indicates current image depth.



Depth Marker Indicator

When depth markers are enabled, the indicator is highlighted in light green.



Gain Indicator Shows gain levels from 0-100%.



Run/Freeze Indicator

When the system is in freeze mode, the indicator is shown in red and blinks briefly every second.



Storage Device Indicator

When a storage device is connected, the indicator icon is shown in solid grayscale. When the storage device is full or has errors, the indicator is displayed with a red "!" overlay.



Printer Indicator

When a printer is connected, the indicator is shown in solid grayscale. If the printer has an error condition, the indicator is displayed with a red "!" overlay.



Display Screen Information



AC Power Indicator

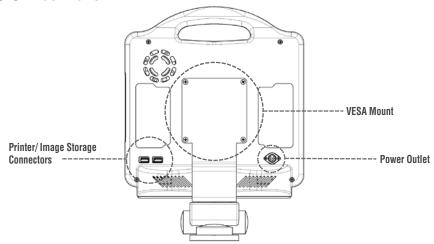
The indicator is shown in solid grayscale when connected to AC wall power and is shown as a dark gray outline when disconnected.



Battery Indicator

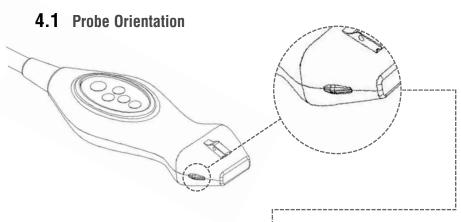
The 5 charge levels for the batteries are displayed as shown. When the unit is recharging, the indicator is green for all 5 levels. When the unit is under battery power, the console battery indicator changes to yellow at 40% and red/blinking at 20% of remaining life. If a battery malfunction is detected, the system will show the battery with a red "!" overlay.

3.3 Back Panel





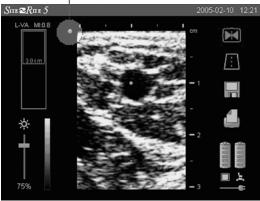
4 Using the Site~Rite* 5 Probe



The Site~Rite 5 vascular access probe includes an orientation bump on the left side of the probe. This bump corresponds to the probe orientation mark located on the Site~Rite 5 display screen.

When using the Site~Rite 5 probe; hold the probe so that the side with the needle guide hook points away from the heart.

Warning: If the probe is damaged in any way, discontinue use immediately. Damage to the scanner may occur.





4.2 Draping the Probe for Sterile Use

When using the Site~Rite 5 probe in a sterile environment, the probe and part of the probe cable must be covered with a sterile, acoustically transparent plastic probe cover.

Warning: Use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.

Caution: Some commercially available probe covers contain latex. Natural rubber latex may cause allergic reactions. Refer to the US FDA alert titled: "Medical Alert: Allergic Reactions to Latex-Containing Medical Devices", issued March 29, 1991. Bard Access Systems distributes sterile probe covers and needle guide kits that do not contain latex.

To purchase sterile plastic probe covers, contact Bard Access Systems' Customer Service at:

Customer Service: (800) 545-0890 www.bardaccess.com

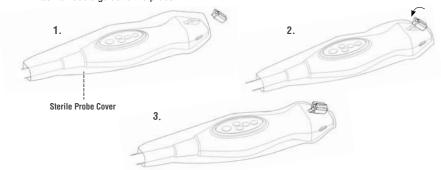
To drape the probe for sterile use:

- 1. Place the probe in the side arm probe holder on the roll stand.
- 2. Apply a layer of non-sterile ultrasonic coupling gel on the acoustic window of the probe head.
- 3. Make sure that the probe cover is fully rolled up.
- 4. Place the probe cover over the probe head, being careful not to wipe off the coupling gel.
- 5. Cover the probe and cable with the probe cover.
- Smooth the probe cover over the acoustic window of the probe head to remove any air bubbles or folds in the sheath.
- 7. Use the latex free poly-bands to hold the probe cover in place.
- 8. Apply a layer of sterile coupling gel to the covered acoustic window.

4.3 Ultrasound Guidance for Vascular Access

To use the Site~Rite 5 system for vascular access:

- 1. Drape the probe for sterile use. Refer to instructions in Section 4.2.
- 2. Attach a needle guide to the probe.



- 3. Slide the appropriately sized needle, beveled edge facing the probe, into the channel on the guide.
- 4. Place the probe against the skin, perpendicular to the target vessel.
- 5. Hold the probe so that the side with the needle guide hook points away from the heart.
- 6. Center the dot markers on the target vessel.
- 7. While keeping the dot markers centered on the target vessel, slowly advance the needle while looking at the screen of the Site~Rite 5 scanner. When the needle approaches the target vessel, you should see the anterior wall indenting. Once puncture occurs, the vessel returns to normal shape.
- 8. Hold the needle, then gently rock the probe away from the need for a smooth separation. The needle guide channel opens, and the needle smoothly disengages from the guide.

To purchase Needle Guides and sterile plastic Probe Covers, contact Bard Access Systems' Customer Service at:

Customer Service: (800) 545-0890 www.bardaccess.com

For instructions on the proper use of the Site~Rite Needle Guides, refer to the Site~Rite* Needle Guide Kits & Ultrasound Probe Cover Kits Instructions for Use.

Warning: When using Site~Rite Needle Guides on the Site~Rite probe, use only sterile, legally marketed plastic probe covers that are 1 mil (0.001 inch or 0.0254 mm) thick.



5 Settings

5.1 Date, Time and Image Size

To modify date, time and image size settings:

- Press the Freeze button (▶|◄) to pause the system.
- Press and hold the Depth button (cm) to enter the time/image size mode. The year field will then be highlighted. Release the Depth button.
- 3. Press the Depth button (cm) to select the desired date or time field to be modified.
- 4. Press the Gain buttons (▼, ▲) to change the selected date or time values.
- After setting the date and time, press the Depth button (cm) to enter the image size fields.
 The current image size will be highlighted.
- 6. Press the Gain buttons $(\mathbf{\nabla}, \mathbf{\Delta})$ to select the desired image size.
- 7. Press the Freeze button (▶|◀) to store the updated settings and resume normal operation.

5.2 Image Parameters

The Site~Rite 5 image may be changed from the factory default settings to a higher contrast image setting.

- To change contrast settings, press and hold the Depth Marker Indicator (/:\) for five seconds.
 Note: The image will switch between image settings.
- To return the Site~Rite 5 image to the original setting, press and hold the Depth Marker Indicator for five seconds.

6 Installing Software

The Site~Rite* 5 Ultrasound System allows software installation through the USB connectors located on the rear of the scanner.

To install software:

- Press the Freeze button (▶ ◀) to pause the system.
- 2. Insert a USB drive into one of the USB connectors located on the rear of the Site~Rite 5 scanner.
- Wait until the storage device icon is illuminated before proceeding.
- 4. Simultaneously press and hold the Gain buttons (▲▼) until the configuration screen appears.
- 5. When the configuration screen appears, simultaneously press and hold the Depth button (cm) and Depth Marker button (/:\) until the software installation process begins.

Note: The Site~Rite 5 System will automatically upload the software from the attached USB drive.

Note: The screen will appear blank and/or inactive during the software installation process.

- 6. When a blinking cursor appears, power off the Site~Rite 5 scanner.
- 7. Disconnect the USB drive.
- 8. Power on the Site~Rite 5 scanner.
- 9. Verify that the correct software version appears on the upper left hand corner of the screen.
- Resume normal operation.



7 Calibrating the Internal Battery

The Site~Rite 5 internal battery may occasionally require calibration to ensure the battery power meter is accurate. The following icon indicates that the Site~Rite 5 battery requires calibration.

To calibrate the Site~Rite 5 Internal Battery:

- 1. Disconnect all Site~Rite 5 power sources.
- Power on the Site~Rite 5 scanner and operate on internal battery power until the system powers off.
- Connect the Site~Rite 5 scanner to the Site~Rite 5 combination A/C adapter and battery charger to recharge the internal battery.

Note: At least six hours of charge time is recommended to fully charge the Site~Rite 5 internal battery.

- 4. Disconnect all Site~Rite 5 power sources.
- Power on the Site~Rite 5 Ultrasound System and operate on internal battery power until the system powers off.

Note: The internal battery is now calibrated.

6. Connect the Site~Rite 5 scanner to the Site~Rite 5 combination A/C adapter and battery charger to recharge the internal battery and continue normal use.



8 Warranty

The manufacturer, Bard Access Systems, warrants this product against defects in material and work-manship for a period of one year from the date of original purchase, and agrees to repair, or at Bard Access Systems' discretion, replace any defective unit free of charge. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. This warranty does not cover damages resulting from misuse, abuse, modification, or alteration of the Site~Rite 5 System.

The following actions void the warranty of the Site~Rite 5 System:

- · Opening or servicing the scanner or the probe housing.
- Removal of system labels by anyone other than by Bard Access Systems authorized service personnel.
- Opening or servicing the battery pack or the combination A/C adapter and battery charger by anyone other than Bard Access Systems authorized service personnel.
- Connecting the Site~Rite 5 scanner to any power source other than the Site~Rite 5 combination A/C adapter and battery pack.
- Connecting the Site~Rite 5 scanner to any A/C adapter other than the one provided with the scanner.
- Connecting the Site~Rite 5 System to any unauthorized accessory.



9 Technical Specifications

9.1 Operating and Storage Conditions

Operating Temperature: 59°F to 100°F (15°C to 38°C)
Storage Temperature: 50°F to 95°F (10°C to 35°C)

Operating Humidity: 5% to 85% Relative Humidity (non-condensing)

Storage Humidity (packaged): 5% to 95% Relative Humidity (non-condensing)

Storage Humidity (unpackaged): 5% to 85% Relative Humidity (non-condensing)

9.2 Scanner Specifications

Dimensions: 12" W x 12" H x 5" D

Weight: 10 lbs.

Power Sources: AC adapter, Internal and External DC Battery Pack

Power Consumption: 82 Watts Maximum

Monitor Size: 12.1" diagonal

IEC 60601- 1: Class II, Type BF Applied Part, Continuous Operation, Internally Powered

Equipment, Not Category AP or APG Equipment, Not protected against

ingress of water.

9.3 Probe Acoustic Output Specifications

Description of Probe	Operating Mode	I _{spta.} X (X denotes statisti- cally determined maximum)	FDA I-spta.3 Published Values	MI X (X denotes statistically determined maximum)	FDA MI Published Values
L-VA	В	78.2mW/cm ²	Peripheral Vessel < 720 m W/cm ² Cardiac < 430 mW/cm ²	1.1	Peripheral Vessel < 1.9 Cardiac < 1.9
			Fetal Imaging & Other** < 94 mW/cm ²		Fetal Imaging & Other** < 1.9

**Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic,

All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2 [1] and UD-3 [2], and following the calibration procedures given in Appendices B, C, D and E of the 1985 FDA 510(k) Guide, and Part A, Sections III-IV, and Appendices A, B, C and D of the 1989 FDA 510(k) Guide, and the Track 1 and Track 3 reporting requirements of the September 30, 1997 Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

Caution: The adverse biological effects of ultrasound on tissue appear to be threshold effects. When tissue is repeatedly exposed to ultrasound, with intervals in between, there will likely be no cumulative biological effect. If however a certain threshold has been passed biological effects may occur. While the Site~Rite 5 acoustic output parameters fall well below all FDA thresholds for adverse biological effects, any given Ultrasound Procedure should be performed using the principle of ALARA (As Low As Reasonably Achievable). The licensed medical practitioner should limit the time of patient exposure to ultrasonic radiation using the principle of ALARA.

The system meets the output display standard for mechanical index (MI). A real time display of the MI is located in the upper left hand corner of the screen. The MI is displayed in increments of .1 with an accuracy of +/- .09. This index is modified as the system focus is changed with the "CM" button on the front panel. For more in-depth information concerning what the MI values mean see the following reference:

- Duck F.A., The Meaning of Thermal Index (TI) and Mechanical Index (MI) values, BMUS Bulletin, Nov. 1997, p. 36-40.

9.4 Probe Specifications

L-VA: Linear Vascular Access Probe

5 -10 MHz Frequency:

Elevation Focus: 1.8 cm Maximum Scan Depth: 6.0 cm Scan Width: 1.9 cm

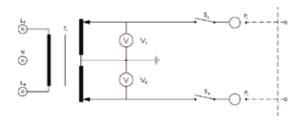
Lateral Foci:

Focal Depth
0.6 cm
1.5 cm
3.0 cm
5.0 cm



9.5 Power Supply Specifications

Note: For 240 V applications use only center tapped 240 VAC single phase power as shown below.



A/C Adapter Specifications

Input Voltage: 100-240 VAC, 50/60 Hz.

Input Current (Max): 1 Amp

Internal Battery Pack Specifications

Battery Chemistry: Lithium Ion Nominal Output Voltage: 10.8 VDC

Output Current (Max): 6 Amps

Output Voltage: 15 VDC
Output Current (Max): 6 Amps

Output Power (Full Charge): 52 Wh System Run Time on Full Charge: 1.0 Hours

Charge Time (Full): 1.75 Hours

Combination A/C Adapter Auxiliary Battery Specifications

Input Voltage: 100-240 VAC, 50/60 Hz. Input Current (Max): 1 Amp

A/C Adapter Output Voltage: 15 VDC
A/C Adapter Output Current (Max): 7 Amps

Nominal Battery Output Voltage: 10.8 VDC

Battery Output Current (Max): 6 Amps Battery Chemistry: Lithium Ion

Output Power (Full Charge): 95 Wh

System Run Time on Full Charge: 2.5 Hours

Battery Charge Time (Full): 3 Hours

9.6 Standards Information

The Site~Rite 5 Ultrasound System is designed to comply with applicable sections of the following International Standards:

- UL 60601-1: 2003, Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1: 1988, Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-1-1: 2000, Medical Electrical Equipment Part 1-1: General Requirements for Safety -Collateral Stanard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2: 2004, Medical Electrical Equipment Part 1-2: General Requirements for Safety -Collateral Stanard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37:2005, Medical Electrical Equipment Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
- NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3:2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- EN 55011:2000 Class A Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment -Radio Distrubance Characteristics-Limits and Methods of Measurement

10 Disposal Information



To return the Site~Rite 5 System for end of life recycling, please contact your nearest Bard sales or distributor office in the country of purchase.

Warning: Always properly dispose of dead battery packs in accordance with local regulations. Improper disposal may present an environmental hazard.



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